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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/12/2005

Greg Swords

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JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,843	SWORDS, GREG	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/14/2008 with respect to claims 1-11, 14-23 have been fully considered but they moot in view of the new grounds for rejection.
2. Applicant's arguments filed 3/14/2008 with respect to claims 12-13 have been fully considered but they are not persuasive. Applicant failed to amend claims 12-13, yet the arguments state that the rejection is moot due to claim amendments. Examiner considers the original rejection to be proper, and is therefore maintaining the previously applied rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11,14-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not support the amendment including "the mesh embedded in the sheet of resin such that resin is formed around at least a portion of the mesh, and in that portion, the resin fills the interstices of the mesh and is in contact with all surfaces of the mesh".

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-11,14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al. (Pub. No.: US 2002/0120348) in view of Morgan (U.S. Pat. No.: 5,380,328).

7. Melican discloses a composite surgical implant comprising a sheet of thermoplastic resin 12 (para 27, 50) and a mesh 14 (para 36, 38) comprising bridges separated by interstices, the mesh embedded in the sheet of resin such that resin is formed around at least a portion of the mesh filling the interstices of the mesh and in contact with all surfaces of the mesh (fig. 1-3, para 26). Examiner considers the resulting implant to be bendable by hand because of the polymeric material used (see para 27).

8. However, Melican fails to show a metal mesh. Morgan teaches the use of titanium metal mesh 46 (see abstract and fig. 5) sandwiched between polymeric sheets (fig. 5) resulting in a strong and bendable implant for conforming to the profile of a defect in a human cranium. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the implant as disclosed by Melican with a titanium mesh as taught by Morgan to provide a strong and bendable implant structure for conforming to the profile of a defect in a human cranium.

9. With respect to claims 3-4, Melican discloses a barrier 16 (see fig. 3) on the top or bottom surface (para 25). The bottom surface of Melican is porous (fig. 3 and para 26). The implant is porous throughout, and the pores are sized to allow fibrovascular ingrowth (para 23). The thermoplastic resin comprises polyethylene (para 50).

10. Melican fails to show HDPE material. Morgan teaches the use of a porous substrate with HDPE, (col. 4 lines 1-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the implant of Melican with the HDPE material as taught by Morgan, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

11. Melican fails to show a surgical screw or bone anchor passing through the implant. Morgan teaches the use of openings for receiving a surgical screw col. 6 lines 42-48) resulting in a means for attaching the implant to bone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the implant as disclosed by Melican with an opening for receiving a surgical screw as taught by Morgan to provide a means for attaching the implant to bone. Morgan further teaches that the implant can further be cut to conform to the shape of the defect (col. 6 lines 27-30).

12. Melican in view of Morgan fails to show specific disclosure of the implant being used in the orbit. It would have been obvious to one of ordinary skill in the art to use the craniofacial implant as taught by Melican in view of Morgan in an orbit, the motivation

being: treating an orbital defect. Such a use is well known in the art; it is further known that craniofacial implants can serve as orbital implants. With respect to claim 18, Melican discloses a top smooth barrier surface and a bottom porous surface (see fig. 3). It would have further been obvious to one of ordinary skill in the art to position the smooth barrier surface towards the orbit, since both sides of the implant comprise both smooth barrier surfaces and porous surfaces and are thus equally suitable to face the orbit.

13. With respect to claims 22-23, Melican discloses an implant comprising a sheet of polyethylene (para 50) with pores that are sized between 20-500 microns, and Morgan teaches the use of polyethylene barriers (col. 4 lines 1-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the implant as disclosed by Melican with a polyethylene barrier as taught by Morgan for the purpose of providing a microporous barrier surface.

14. Claims **12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable Wellisz (U.S. Pat. No. 5,743,913) in view of Morgan (U.S. Pat. No. 5,380,328), further in view of Cohen et al. (U.S. Pat. No. 6,087,553)

15. Wellisz discloses a surgical implant comprising a planar sheet of a thermoplastic resin and a surgical grade metal mesh contained therein (col. 3 lines 43-48), and said implant is able to be bent or displaced by manipulation by hand (col. 2 line 62-col. 3 line 6). However, Wellisz does not disclose a smooth barrier surface. Morgan teaches the use of a barrier (PTFE with a HDPE backing, col. 4 lines 1-6) for the purpose of

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precluding the passage of unwanted biological cells (see abstract). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wellisz to include a smooth barrier surface on the opposite side of the porous thermoplastic resin (tissue ingrowth region), the motivation to combine being: preventing unwanted cellular infiltration from one side of the implant.

16. Wellisz in view of Morgan is explained supra. In addition, Morgan teaches heat fusing polyethylene barrier surfaces to the implant (see abstract of Morgan). However, Wellisz and Morgan lack the use of a mold with applied heat and pressure. Cohen teaches using heat and pressure to secure polyethylene to an implant surface for the purpose of creating an interface between the polyethylene and the implant surface that is securely fixed and does not allow micro and macro motion between the two materials (see abstract of Cohen). Therefore it would have been obvious to one of ordinary skill in the art to modify the methods of Wellisz and Morgan to include the use of a mold with applied heat and pressure, the motivation to combine being: providing an interface between the polyethylene and the implant surface that is securely fixed and does not allow micro and macro motion between the two materials. With respect to claim 13, Morgan teaches the use of a barrier on both sides or just one side of an implant if desired (see all figures of Morgan). The examiner considers it to be well within the skill of an ordinary worker in the art, in view of the teachings of Morgan, to provide a thin sheet of PE to be heat fused at either the top or the bottom of the mold for the purpose of securing it to the implant.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774